JUN 19 2014

510(K) SUMMARY

(K130694)

1. Submitter / Applicant: June /18/2014

KJ Meditech Co., Ltd.
959-21 Daechon-dong, Buk-gu, Gwang-ju, 500-470, South Korea
Phone : +82-62-972-5476 Fax : +82-62-973-2809

2. Submission Correspondent:

Priscilla Chung
LK Consulting Group USA, Inc.
2651 E Chapman Ave Ste 110,
Fullerton CA 92831
Tel: 714-202-5789
Email: juhee.c@lkconsultinggroup.com

3. Device Name :

Trade Name	:	JR Implant System
Common Names	:	Abutment, Dental, Endosseous implant
Classification Name	:	Implant, Endosseous, Root-Form
Regulation	:	21 CFR 872.3640, DZE

4. Predicate Device :

NobelReplace Tapered Conical Connection (K062566)
Manufactured by Nobel Biocare USA LLC

5. Device Description :

The JR Implant system is made of Titanium 6AL 4V ELI alloy intended to be surgically placed in the bone of the upper or lower jaw arches for loading after a conventional healing period. The implants may be used to replace one or more missing teeth. The systems are similar to

other commercially available products based on the intended use, the technology used, the claims, the material composition employed and performance characteristics. The surface of the implant has been treated with R.B.M (Resorbable Blast Media).

The fixtures are offered in the following length and diameter.

- Narrow Platform Fixture: 3.5mm Dia. x 8.6mm(L) / 10.6mm(L) / 12.1mm(L) / 13.6mm(L) / 16.6mm(L)
- Regular Platform Fixture : 4.3 mm Dia. x 8.6mm(L) / 10.6mm(L) / 12.1mm(L) / 13.6mm(L) / 16.6mm(L)
- Wide Platform Fixture : 5.0mm Dia x 8.6mm(L) / 10.6mm(L) / 12.1mm(L) / 13.6mm(L) / 16.6mm(L)
- 6.0 Platform Fixture : 6.0mm Dia. x 8.6mm(L) / 10.6mm(L) / 12.1mm(L) / 13.6mm(L) / 16.6mm(L)

There are five different types of abutments offered and they are provided straight only.

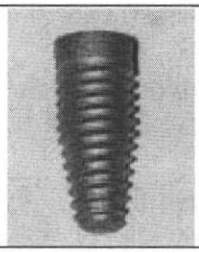
- Esthetic Abutment
- EZ Abutment
- Healing Abutment
- Cover Screw
- Temporary Abutment

5 Intended For Use :

The JR Implant System is indicated for use in partially or fully edentulous mandibles and maxillae, in support of single or multiple-unit restorations including; cemented retained, screw retained, or overdenture restorations, and terminal or intermediate abutment support for fixed bridgework. The JR Implant System are for single and two stage surgical procedures. These systems are intended for delayed loading.

6. Substantial Equivalence :

Item	Subject Device	Predicate Device
510(K) Number	N/A	K062566
Device Name	JR Implant System	NobelReplace Tapered Conical Connection
Manufacturer	KJ Meditech Co., Ltd.	Nobel Biocare USA LLC
Indications for Use	Intended for use in partially or fully edentulous mandibles and maxillae, in support of single or multiple-unit restorations including; cement-retained, screw-retained, or overdenture restorations, and terminal or intermediate abutment support for fixed bridgework.	Intended for use in partially or fully edentulous mandibles and maxillae, in support of single or multiple-unit restorations including; cement-retained, screw-retained, or overdenture restorations, and terminal or intermediate abutment support for fixed bridgework.

Design	• Implant Type: Bone Level Implant • Connection Type: Internal tri-lobe connection • Neck Design: Straight walled neck with micro-thread provides crestal seal. • Body Design: Tapered design enables placement near impringing anatomical structures while maximizing prosthetic table diameter for natural emergence profile.	• Implant Type: Bone Level Implant • Connection Type: Internal tri-channel connection • Neck Design: Straight walled neck with circumferential thread provides crestal seal. • Body Design: Tapered design enables placement near impringing anatomical structures while maximizing prosthetic table diameter for natural emergence profile.
Fixture Appearance		
Fixture Surface Treatment	RBM Treatment on the fixture body	TiUnite® surface treatment.
Fixture Material	Ti 6Al 4V ELI, ASTM F136	Pure titanium, ASTM F67
Fixture Sterile	Yes	Yes
Sterilization Method	Gamma	Gamma
Fixture Diameters	3.5mm 4.3mm 5.0mm 6.0mm	3.5mm 4.3mm 5.0mm 6.0mm
Fixture Lengths	8mm – 16.0 mm	8mm – 16.0 mm
Abutment Surface Treatment	Anodizing	Anodizing
Abutment material	Ti 6Al 4V ELI, ASTM F136	Pure titanium, ASTM F67
Cover screw Surface Treatment	Anodizing	Anodizing
Cover screw material	Ti 6Al 4V ELI, ASTM F136	Pure titanium, ASTM F67
Healing Abut Surface Treatment	Anodizing	Anodizing
Healing Abut material	Ti 6Al 4V ELI, ASTM F136	Pure titanium, ASTM F67
Temporary Abut Surface Treatment	Anodizing	Anodizing
Temporary Abut material	Ti 6Al 4V ELI, ASTM F136	Pure titanium, ASTM F67
Abutment Type	For Narrow Platform Fixture For Regular Platform Fixture For Wide Platform Fixture For 6.0 Platform Fixture	For Narrow Platform Fixture For Regular Platform Fixture For Wide Platform Fixture For 6.0 Platform Fixture
Cover Screw Type	For Narrow Platform Fixture For Regular Platform Fixture For Wide Platform Fixture For 6.0 Platform Fixture	For Narrow Platform Fixture For Regular Platform Fixture For Wide Platform Fixture For 6.0 Platform Fixture
Healing Abut Type	For Narrow Platform Fixture For Regular Platform Fixture For Wide Platform Fixture	For Narrow Platform Fixture For Regular Platform Fixture For Wide Platform Fixture

	For 6.0 Platform Fixture	For 6.0 Platform Fixture
Temporary Abutment	For Narrow Platform Fixture For Regular Platform Fixture For Wide Platform Fixture For 6.0 Platform Fixture	For Narrow Platform Fixture For Regular Platform Fixture For Wide Platform Fixture For 6.0 Platform Fixture
Product Code	DZE	DZE

The JR Implant system is substantially equivalent in intended use, design and performance to the predicate devices.

The differences between the subject device and the predicate device are the titanium grade and surface treatment of the fixture; however, testing data such as biocompatibility testing provided in the submission proves that this difference would not raise issues in safety and performance. Therefore, we claim that the proposed device is substantially equivalent to the predicate device.

7. Performance Testing

- Biocompatibility testing on the proposed JR Implant System has been completed.

The biocompatibility test results show that the materials used in the design and manufacture of the components of the proposed device are non-toxic and non-sensitizing to biological tissues consistent with its intended use. The following biocompatibility tests were completed.

-ISO Cytotoxicity -ISO Sensitization

-ISO Intracutaneous reactivity

- Sterilization validation and surface treatment analysis were also conducted on JR Implant System.

8. Conclusion

Based on the information provided in this premarket notification KJ Meditech Co., Ltd concludes that the JR Implant System is substantially equivalent to the predicate device as described herein.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

June 19, 2014

KJ Meditech Co., Ltd.
C/O Ms. Priscilla Chung
Regulatory Affairs Consultant
LK Consulting Group USA, Inc.
2651 East Chapman Avenue, Suite 110
Fullerton, CA 92833

Re: K130694
Trade/Device Name: JR Implant System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: DZE, NHA
Dated: May 14, 2014
Received: May 20, 2014

Dear Ms. Chung:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mary S. Runner -S

Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indication for use Statement

510(k) Number (If known) : K130694

Device Name : JR Implant System

Indication for use :

The JR Implant System is indicated for use in partially or fully edentulous mandibles and maxillae, in support of single or multiple-unit restorations including; cemented retained, screw retained, or overdenture restorations, and terminal or intermediate abutment support for fixed bridgework. The JR Implant System is for single and two stage surgical procedures. These systems are intended for delayed loading.

Prescription Use X AND/OR **Over-The-Counter** _____
(Part 21 CFR 801 Subpart D) (Part 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Sheena A. Green -S
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